

### REMARKS

In the Office Action, the Examiner has objected to the specification and to claims 2, 9, 14 and 20 for various informalities. Claim 2 has been rejected under 35 U.S.C. § 112, first paragraph, for lack of antecedent basis in the specification. Claims 1-4, 10-12 and 16-18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Dobak, III (U.S. Patent No. 5,957,963). Claim 5 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dobak, III. Further, claims 1-4 and 6-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lalonde et al. (U.S. Patent No. 6,589,234) in view of Dobak, III.

In response to the Office Action, the specification and claims 2, 9, 14 and 20 have been amended to address various informalities noted by the Examiner. Specifically, these amendments replace the incorrect notation " $p_t$ " for tip temperature with the correct notation " $T_t$ ", and they cite the appropriate dimensional relationship between the supply tube and the capillary tube. In addition, independent claims 1, 10 and 16 have been amended to require that the fluid refrigerant be cooled to approximately  $-45^{\circ}\text{C}$  at a pressure of approximately 400psia before it is introduced into the cryo-chamber. To avoid redundancy, claim 7 has been cancelled and claims 3 and 19 have been amended by deleting limitations now presented in independent claims 10 and 16. Further, claim 8 has been amended to depend from a still pending claim. Support for these amendments can be found in the specification on page 8, lines 23-29. Claims 1-6 and 8-20 remain pending.

Amendments are presented herein to improve the form of the specification. In addition, amendments to the claims have been presented herein to improve the readability of the claims and to point out the features which distinguish the present invention over the cited art. Reconsideration of claims 1-6 and 8-20 is respectfully requested in view of the above-recited amendments and the arguments set forth below.

#### Objections to the Specification

The Examiner has objected to the disclosure because of an informality regarding the notation for tip temperature. Specifically, the Examiner has noted that on page 6, lines 1 and 2, the specification recites " $p_t$ " when it should recite " $T_t$ ". This informality has now been corrected by deleting " $p_t$ " and inserting " $T_t$ " therefore at the appropriate locations in the specification.

#### Objections to the Claims

Claim 2 has been objected to because of language that is unsupported by the specification. Specifically, the Examiner has noted that the dimensional relationship between the supply tube " $l_s$ " and the capillary tube " $l$ " is not in accordance with the disclosure provided by the specification. In order to bring claim 2 into agreement with the specification, claim 2 has been amended, as suggested by the Examiner, to indicate that the length of the supply tube " $l_s$ " is greater than or equal to the length of the capillary tube " $l$ ".

Further, claims 9, 14 and 20 were objected to by the Examiner because of improper recitations of the term “p<sub>i</sub>” when the proper recitation would be “T<sub>i</sub>”. Appropriate corrections have been made to claims 9, 14 and 20 by deleting the term “p<sub>i</sub>” and inserting “T<sub>i</sub>” where appropriate.

#### Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claim 2 under 35 U.S.C. § 112, first paragraph, for lack of antecedent basis in the specification. Applicant notes that the basis for the rejection of claim 2 is the same as the basis for the objection to claim 2 above. Accordingly, the Applicant respectfully contends that amended claim 2 now has antecedent basis in the specification and that the basis for rejection under 35 U.S.C. §112, first paragraph, has been overcome.

#### Rejections Under 35 U.S.C. § 102(b)

Claims 1-4, 10-12 and 16-18 have been rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Dobak, III (U.S. Patent No. 5,957,963).

In response, as indicated above, independent claims 1, 10 and 16 have been amended to require a fluid refrigerant be cooled to approximately -45°C at a pressure of approximately 400 psia before it is introduced into the cryo-chamber. Unlike the presently claimed invention, Dobak III does not teach or suggest a structure that is intended to operate in such an environment. More specifically, while Dobak, III mentions compressing

and condensing the fluid refrigerant prior to its introduction into a chamber, the purpose for doing so is far different. Accordingly, the operational parameters are also quite different. Unlike the present invention, the invention in Dobak, III is directed towards inducing hypothermia in selected internal organs. The temperatures required for this operation (i.e. around 0°C) is far different from the temperatures contemplated by the present invention for cryoablating tissue (e.g. -84°C). Importantly, Dobak, III does not teach or suggest that the fluid refrigerant may be cooled to the temperatures contemplated by the presently claimed invention and, therefore, does not disclose a structure, and cooperation of structure, as claimed for the present invention that is capable of generating such temperatures.

Accordingly, the Applicant respectfully contends that amended independent claims 1, 10 and 16 are not anticipated by the cited reference. Further, since claims 2-4, 11, 12, 17 and 18 depend directly or indirectly from amended independent claims 1, 10 or 16, these claims are likewise allowable in view of the cited reference. For the reasons set forth above, Applicant believes the basis for rejecting claims under 35 U.S.C. § 102(b) has been overcome, and the rejections should, therefore, be withdrawn.

#### Rejections Under 35 U.S.C. § 103(a)

Claims 1-4 and 6-20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lalonde et al. (U.S. Patent No. 6,589,234) in view of Dobak, III.

In response, independent claims 1, 10 and 16, as indicated above, have been amended to require a fluid refrigerant be cooled to approximately  $-45^{\circ}\text{C}$  at a pressure of approximately 400 psia before it is introduced into the cryo-chamber. Importantly, the fluid refrigerant, under the conditions described above, is in a liquid state. Accordingly, the fluid refrigerant is introduced into the cryo-chamber in a substantially liquid state to cool the cryo-chamber as it changes from a liquid to a gaseous phase. None of the cited references, individually or in combination, teach or suggest the structure or cooperation of structure claimed in the present invention.

In contrast to the present invention, Lalonde et al. do not teach or suggest cooling the fluid refrigerant to a liquid phase prior to introduction into the cryo-chamber. Instead, Lalonde et al. teach introducing a mixed liquid and gas phase refrigerant into the cryo-chamber. As a consequence of this mixed phase refrigerant, the refrigerant cools through two different thermodynamic changes. The first is a Joule-Thompson throttling effect and the second is a liquid to vapor phase change (see Lalonde et al., col. 6, lns 34-44). In contrast, the presently claimed invention requires structure that will maintain the refrigerant in a liquid state as it passes through the catheter to the cryo-chamber. In the cryo-chamber, cooling is accomplished primarily through a substantially liquid to vapor phase change.

With regard to Dobak, III, in line with the above arguments, Dobak, III does not teach or suggest operating at the temperatures and pressures contemplated by the presently claimed invention. Further, Applicant respectfully contends that there is no

teaching or suggestion in Lalonde et al. or Dobak, III to motivate a person of ordinary skill in the art to combine the cited references to arrive at the presently claimed invention. As indicated above, the cited references are directed toward different applications. The Lalonde et al. invention is directed toward cryoablation of tissue and mapping tissue. Dobak, III is directed toward inducing hypothermia in selected internal organs. Importantly, there are significant differences in operating temperatures between a cryoablating device and a device for inducing hypothermia in selected internal organs.

Accordingly, Applicant contends that amended independent claims 1, 10 and 16 are nonobvious with respect to the cited combination of references. Further, since claims 2-4, 6-9, 11-15 and 17-20 depend directly or indirectly from amended independent claims 1, 10 and 16, they are also nonobvious with respect to the cited combination of references.

Additionally, claim 5 has also been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dobak, III (U.S. Patent No. 5,957,963). As indicated above, Applicant contends that independent claim 1, as amended, is now nonobvious with respect to the cited combination of references. Thus, Applicant respectfully contends that since claim 5 depends indirectly from amended claim 1, it is also nonobvious with respect to the cited combination of references.

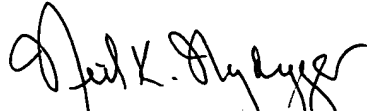
For the reasons set forth above, Applicant believes the basis for rejecting claims under 35 U.S.C. § 103(a) has been overcome, and the rejections should, therefore, be withdrawn.

The references cited by the Examiner, but not relied on for the rejection of claims, have been noted.

In conclusion, Applicant respectfully asserts that claims 1-6 and 8-20 are patentable for the reasons set forth above, and that the application is now in a condition for allowance. Accordingly, an early notice of allowance is respectfully requested. The Examiner is requested to call the undersigned at 619-688-1300 for any reason that would advance the instant application to issue.

Dated this 12<sup>th</sup> day of April, 2005.

Respectfully submitted,



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Filed:	July 24, 2003	)	
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CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24<sup>th</sup> day of April, 2005.



DEBRA D. BURNS  
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Transmitted: Response to the Office Action dated November 15, 2004, Petition for Extension of Time, and Check for Petition for Extension of Time.

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